IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellants:	Bruce S. Ellingboe et al.	Attorney Docket:	CV0290US
Serial No.:	09/963,878	Group Art Unit:	3762
Filed:	September 26, 2001	Examiner:	Leslie R. Deak
For:	BLOOD PERFUSION SYSTEM		

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Appeal Brief is presented in support of the Notice of Appeal to the Board of Patent Appeals and Interferences, filed May 16, 2005, from the Final Rejection of claims 1 and 3 to 12 of the above-identified application, as set forth in the Final Office Action mailed February 15, 2005. The period for filing the Appeal Brief has been extended from July 16, 2005, to August 16, 2005, by the enclosed Petition for Extension of Period for Response. Enclosed is a check in the amount of $620.00 to cover the fees for filing an appeal brief ($500.00) and for a one month extension of time ($120.00). Appellants respectfully request reconsideration and reversal of the Examiner's rejections of the pending claims.

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Date: August 16, 2005 **Signature:** Jodi Jung

Name: Jodi Jung

As required by 37 C.F.R. § 41.37, this Brief contains the following items under the headings and in the order suggested therein.

TABLE OF CONTENTS

(1) REAL PARTIES IN INTEREST

The real parties in interest of the above-captioned patent application are the assignee, Cobe Cardiovascular, Inc., and its parent, Sorin Group S.p.A.

(2) RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellants or Appellants' representative that will have a bearing on the Board's decision in the present appeal.

(3) STATUS OF CLAIMS

Claims 2 and 13 to 101 are cancelled. Claims 1 and 3 to 12 are pending in this application. Claims 1 and 3 to 12 are rejected and are the subject of this appeal.

(4) STATUS OF AMENDMENTS

No amendments have been filed or entered after the outstanding Final Rejection.[1]

[1] The Examiner and Cecilia Jaisle of our office discussed the rejections outstanding in this application during a phone conference on June 28, 2005, but no agreement was reached.

(5) SUMMARY OF INVENTION

The invention as recited in claim 1 relates to an extracorporeal blood perfusion system for receiving venous blood from a patient and returning oxygenated blood to the patient in a cardiopulmonary bypass procedure. Page 4, lines 9 to 21. An extracorporeal blood perfusion system, such as 1, shown in FIG. 1, includes a disposable assembly 100, shown in FIG. 2A, with a cartridge 120, shown in FIG. 2A, and a plurality of interconnected tubing lines 104, 110, 178, 180, 190, etc., shown in FIG. 2A. The cartridge has a plurality of internal fluid passageways, shown in FIGS. 19 and 20. One tubing line fluidly interconnects with one fluid passageway. FIG. 2A. The disposable assembly has an oxygenator 112, shown in FIG. 8A, connected in a blood circuit, shown in FIG. 2A. The disposable assembly defines the blood circuit for receiving venous blood from the patient and transferring oxygenated blood to the patient in a cardiopulmonary bypass procedure. The disposable assembly 100 has a reservoir 106, shown in FIG. 11, connected to receive venous blood from the patient through a second tubing line.

The extracorporeal blood perfusion system also includes a control unit 10, shown in FIG. 1, with a component interface region 12, shown in FIG. 1. The component interface region has a cartridge interface region 20, shown in FIG. 4, which operatively interfaces with the cartridge 120, and a pump 31, shown in FIG. 1, which operatively interfaces with the blood circuit for pumping venous blood through the blood circuit. The component interface region has a flow control clamp 46, shown in FIG. 4, to control venous blood flow through the second tubing line to the reservoir.

This summary does not provide an exhaustive or exclusive view of the present subject matter, and Appellants refer to the appended claims and their legal equivalents for a description of the invention.

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1, 3, 4, and 6 to 12 are rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Pat. No. 5,462,416 to Dennehey et al. ("Dennehey") in view of U.S. Pat. No. 5,385,540 to Abbott ("Abbott").

Claim 5 is rejected under 35 U.S.C. § 103(a) as unpatentable over Dennehey, in view of U.S. Pat. No. 5,820,579 to Plotkin ("Plotkin"), in view of Abbott.

(7) ARGUMENTS

A) The Applicable Law under 35 U.S.C. § 103(a)

Under section 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. *M.P.E.P. § 2141. Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966).

The Supreme Court reaffirmed and relied upon the *Graham* three pronged test in its consideration and determination of obviousness in the fact situations presented in *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 189 USPQ 449, *reh'g denied*, 426 U.S. 955 (1976) and *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 163 USPQ 673 (1969).

1. Scope and Content of the Prior Art

a. Dennehey

Dennehey describes a peristaltic pump tube cassette for a blood processing system to centralize pumping, valving and pressure sensing functions (col. 1, line 36, to col. 2, line 43). The blood donor from whom blood is processed may be donating blood components for autologous use or for personal use in an anticipated surgical or medical procedure. In a single needle fluid circuit, the Dennehey blood processing system processes a donor's blood and returns a portion of processed blood to the donor (FIG. 19, col. 16, line 25, to col. 18, line 37). Whole blood (WB) is withdrawn from a donor and mixed with anti-coagulant. Anti-coagulated WB is separated into red blood cells (RBC) and platelet rich plasma (PRP). RBC is conducted to a reservoir 70, to a cassette 22A and is returned to the donor. PRP enters a second stage compartment 36 for separation into platelet poor plasma (PPP) and concentrated platelets (PC). A portion of PPP returns to the donor with RBC, another portion of PPP resuspends separated PC, and other PPP portions serve additional processing purposes in the Dennehey system. Resuspended PC is conveyed to collection containers 96 and remaining PPP is stored for therapeutic purposes.

In a Dennehey double needle fluid circuit (FIG. 20, col. 18, line 38, to col. 20, line 5), cassette 22A directs anti-coagulated WB from a donor by a first needle 49 into first stage compartment 34. Cassette 22A directs separated RBC from the first stage compartment 34 back to the donor through a second needle 48. Separated PRP is conducted from first stage compartment 34 to cassette 22C. Tubing branch 80 takes PRP from cassette 22C to second stage compartment 36 for separation into PPP and PC. A portion of PPP returns to the donor with RBC

during the return cycle. Another portion of PPP resuspends PC after separation and other PPP is collected for processing and therapeutic purposes.

Because the Dennehey system does not compromise or bypass the cardiopulmonary system, the system does not include and has no need for a blood oxygenator.

b. Abbott

Abbott describes a system for delivering cardioplegic solution to the heart during open-heart cardiac bypass surgery, in cooperation with an extracorporeal blood circuit employing a heart/lung machine (col. 1, line 5, to col. 3, line 16). The cardioplegic delivery system delivers cardioplegic solution to still and protect the heart during the surgical procedure. The heart/lung machine oxygenates and temperature-controls venous blood in an extracorporeal blood circuit, and pumps oxygenated blood to the patient's arterial vasculature. A disposable pump cassette 26 (FIG. 2, col. 5, lines 19 to 53) is described for use only in the cardioplegia delivery system, not in connection with oxygenation and pumping of the patient's blood.

c. Plotkin

Plotkin describes a method and apparatus for creating pulsatile flow in a heart/lung machine of a cardiopulmonary bypass circuit. Cyclically switching blood flow between the arterial supply line and a recycle line, which returns blood to a point upstream of the arterial pump, achieves this pulsatile flow. Pulsatile flow mimics natural heart pumping and improves efficacy of extracorporeal perfusion over systems relying on constant blood flow. (Col. 1, line 13, to col. 3,

line 20). The heart/lung machine includes a venous reservoir to receive venous blood from a patient, an arterial supply line to return oxygenated blood to the patient, a cardiopulmonary circuit including the reservoir, arterial supply line, arterial pump and oxygenator, a recycle line to discharge blood into the circuit upstream of the pump, and a proportioning valve to convey pulsatile pumped blood to the arterial supply and recycle lines.

B) Discussion of the Rejection of Claims 1, 3, 4, and 6 to 12 under 35 U.S.C. § 103(a) as unpatentable over Dennehey in view of Abbott.

Appellants respectfully traverse this rejection as unsustainable. Appellants submit that the outstanding Final Rejection made an improper *prima facie* finding of obviousness. Because the teachings of Dennehey in view of Abbott do not establish the obviousness of the present claims to one of ordinary skill in this art, Appellants respectfully request reversal of this section 103(a) rejection.

1. Scope and Content of the Prior Art

The scope and content of Dennehey and Abbott have been discussed above.

2. Differences between Prior Art and Claims at Issue

a. Differences between Dennehey and Abbott and claims at issue.

First, neither Dennehey nor Abbott teaches or suggests a disposable assembly that oxygenates venous blood and transfers oxygenated venous blood to the patient. Second, neither Dennehey nor Abbott discloses or suggests a disposable assembly, further comprising a reservoir having an inlet connected to

receive venous blood from the patient through a tubing line, or a component interface region, further comprising a flow control clamp for controlling venous blood flow through the tubing line to the reservoir. Third, neither Dennehey nor Abbott discloses or suggests a flow control clamp for controlling venous blood flow through a tubing line to a reservoir.

i. Neither Dennehey nor Abbott suggests an extracorporeal perfusion system having a disposable assembly with an oxygenator connected to a blood circuit, as required by the rejected claims.

The Dennehey peristaltic pump tube cassette for a blood processing system has no blood oxygenator and a blood oxygenator would serve no purpose in the Dennehey system, because the Dennehey system processes a donor's blood and returns the processed blood to the donor without bypassing or compromising the function of the donor's cardiopulmonary system (col. 16, line 25, to col. 20, line 5).

The disposable assembly described by Abbott is a disposable pump cassette 26 (FIG. 2, col. 5, lines 19 to 53), and it is described for use only in the cardioplegia delivery system, not in connection with oxygenation and pumping of the patient's blood. Therefore, Abbot does not teach or suggest an extracorporeal perfusion system having a disposable assembly with an oxygenator connected to a blood circuit.

ii. Neither Dennehey nor Abbott suggests an extracorporeal perfusion system having a disposable assembly with a reservoir to receive venous blood from a patient, as required by the rejected claims.

Neither Dennehey nor Abbott suggests an extracorporeal perfusion system for use in a cardiopulmonary bypass procedure having a disposable assembly with a reservoir having an inlet connected to receive venous blood from a patient through a tubing line.

The Dennehey blood processing system processes a donor's blood and returns processed blood to the donor without compromising or bypassing the donor's cardiopulmonary system (col. 16, line 25, to col. 20, line 5). Dennehey has no disclosure of an extracorporeal perfusion system for use in a cardiopulmonary bypass procedure.

The only reservoir mentioned in Abbott is a water reservoir 38 for heating cardioplegic solution (FIG. 1, col. 4, lines 13 to 28). The disposable assembly of Abbott (Fig. 2, col. 5, lines 19 to 53) is a pump cassette with only pumps, valves and conduits for flowing blood. The Abbott disposable assembly does not contain a reservoir as required by the rejected claims.

iii. Neither Dennehey nor Abbott suggests an extracorporeal perfusion system having a component interface region with a flow control clamp for controlling venous blood flow to the reservoir, as required by the rejected claims.

Neither Dennehey nor Abbott suggests an extracorporeal perfusion system for use in a cardiopulmonary bypass procedure having a component interface

region with flow control clamp for controlling venous blood flowing through a tubing line to the reservoir.

As noted above, the Dennehey blood processing system processes a donor's blood and returns processed blood to the donor without compromising or bypassing the donor's cardiopulmonary system (col. 16, line 25, to col. 20, line 5). Dennehey has no disclosure of an extracorporeal perfusion system for use in a cardiopulmonary bypass procedure.

The only reservoir mentioned in Abbott is a water reservoir 38 for heating cardioplegic solution (FIG. 1, col. 4, lines 13 to 28). Because venous blood does not flow to the Abbott water reservoir, therefore, there is no flow control clamp to control this non-existent venous blood flow.

3. Resolution of the level of ordinary skill in the art.

i. Dennehey in view of Abbott do not suggest to one of ordinary skill in this art an extracorporeal perfusion system having a disposable assembly with an oxygenator connected to a blood circuit, as claimed.

The Dennehey peristaltic pump tube cassette for a blood processing system has no blood oxygenator and a blood oxygenator would serve no purpose in the Dennehey system, because the Dennehey system processes a donor's blood and returns the processed blood to the donor without bypassing or compromising the function of the donor's cardiopulmonary system (col. 16, line 25, to col. 20, line 5). The disposable assembly described by Abbott is a disposable pump cassette 26 (FIG. 2, col. 5, lines 19 to 53), and it is described for use only in the cardioplegia delivery system, not in connection with oxygenation and pumping of the patient's blood. Therefore, Abbot does not teach or suggest an extracorporeal perfusion

system having a disposable assembly with an oxygenator connected to a blood circuit.

Because the Dennehey system has no need for an oxygenator, while the Abbott system does not use an oxygenator in a disposable assembly connected in a blood circuit, Dennehey in view of Abbott do not suggest to one of ordinary skill in this art the presently claimed extracorporeal blood perfusion system requiring, a disposable assembly with an oxygenator.

ii. Dennehey in view of Abbott do not suggest to one of ordinary skill in this art an extracorporeal perfusion system having a disposable assembly with a reservoir to receive venous blood from a patient, as claimed.

Dennehey in view of Abbott do not suggest to one of ordinary skill in this art an extracorporeal perfusion system for use in a cardiopulmonary bypass procedure having a disposable assembly with a reservoir having an inlet connected to receive venous blood from a patient through a tubing line. The Dennehey blood processing system processes a donor's blood and returns processed blood to the donor without compromising or bypassing the donor's cardiopulmonary system (col. 16, line 25, to col. 20, line 5). Dennehey has no disclosure or suggestion of an extracorporeal perfusion system for use in a cardiopulmonary bypass procedure. The Abbott disposable assembly (Fig. 2, col. 5, lines 19 to 53) is a pump cassette with pumps, valves and conduits for flowing blood and contains no reservoir. Because Dennehey does not disclose or suggest an extracorporeal perfusion system for use in a cardiopulmonary bypass procedure and Abbott does not disclose or suggest a blood reservoir, Dennehey in view of Abbott do not suggest to one of ordinary skill in this art an extracorporeal perfusion system as

claimed having a disposable assembly with a reservoir to receive patient venous blood.

iii. Dennehey in view of Abbott do not suggest to one of ordinary skill in this art an extracorporeal perfusion system having a component interface region with a flow control clamp for controlling venous blood flow to the reservoir, as claimed.

The Dennehey blood processing system processes a donor's blood and returns processed blood to the donor without compromising or bypassing the donor's cardiopulmonary system (col. 16, line 25, to col. 20, line 5). The only reservoir in Abbott is a water reservoir, to which venous blood does not flow; therefore, no flow control clamp controls non-existent venous blood flow to a reservoir. Because Dennehey does not disclose or suggest an extracorporeal perfusion system for use in a cardiopulmonary bypass procedure and Abbott does not disclose or suggest a blood reservoir or a flow control clamp for controlling flow to the such a reservoir, Dennehey in view of Abbott do not suggest to one of ordinary skill in this art an extracorporeal perfusion system as claimed for use in a cardiopulmonary bypass procedure having a component interface region with flow control clamp for controlling venous blood flowing through a tubing line to the reservoir.

Appellants respectfully submit that claims 1, 3, 4, and 6 to 12 define an invention unsuggested to one of skill in this art by the cited references.

C) Discussion of the Rejection of Claim 5 under 35 U.S.C. § 103(a) as unpatentable over Dennehey in view of Plotkin in view of Abbott.

Appellants respectfully traverse this rejection as unsustainable. Claim 5 depends from claim 1 and recites a sensor for detecting gaseous bubbles and a valve for diverting flow of the oxygenated blood upon detection of gaseous bubbles. The teachings of Plotkin do not remedy the defects of the combination of Dennehey and Abbott described above. Because the teachings of Dennehey in view of Plotkin in view of Abbott do not establish the obviousness of the present claims to one of ordinary skill in this art, Appellants respectfully request reversal of this section 103(a) rejection.

(8) SUMMARY

For the reasons argued above, claims 1, 3, 4, and 6 to 12 are not properly rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Pat. No. 5,462,416 to Dennehey et al. in view of U.S. Pat. No. 5,385,540 to Abbott, and claim 5 is not properly rejected under 35 U.S.C. § 103(a) as unpatentable over Dennehey, in view of U.S. Pat. No. 5,820,579 to Plotkin, in view of Abbott.

Appellants respectfully submit that the art cited does not render the claim obvious and that the claims are patentable over the cited art. Reversal of the rejections and allowance of the pending claims are respectfully requested.

If any additional fees are due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 16-2312. If a fee is required for

an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our deposit account.

Respectfully submitted,

Date: August 16, 2005

By _____

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CLAIMS APPENDIX

1 (Previously Presented). An extracorporeal blood perfusion system for receiving venous blood from a patient and for returning oxygenated blood to the patient in a cardiopulmonary bypass procedure, comprising:

a disposable assembly including a cartridge and a plurality of interconnected tubing lines, the cartridge having a plurality of internal fluid passageways, wherein a first of the tubing lines is fluidly interconnected with at least one of the plurality of fluid passageways, wherein the disposable assembly comprises an oxygenator connected in a blood circuit, wherein the disposable assembly defines the blood circuit for receiving venous blood from the patient and transferring oxygenated blood to the patient in a cardiopulmonary bypass procedure, and wherein the disposable assembly further comprises a reservoir having an inlet connected to receive venous blood from the patient through a second of the positioned tubing lines; and

a control unit having a component interface region, the component interface region including a cartridge interface region for operatively interfacing with the cartridge, a first pump for operatively interfacing with the blood circuit, wherein the venous blood is pumped through the blood circuit by the first pump, and wherein the component interface region further comprises a flow control clamp for controlling the flow of venous blood through the second tubing line to the reservoir.

2 (Canceled).

3 (Previously Presented). The extracorporeal blood perfusion system of claim 1, wherein the flow control clamp is controllable to maintain at least one of a predetermined relative flow percentage through the second tubing line to the reservoir and a predetermined fluid volume within the reservoir.

4 (Previously Presented). The extracorporeal blood perfusion system of claim 1, wherein the oxygenator is connected in the blood circuit downstream from the reservoir, and wherein the first pump is configured to pump accumulated venous blood from the reservoir through the oxygenator to provide for the transfer of the oxygenated blood to the patient.

5 (Previously Presented). The extracorporeal blood perfusion system of claim 1, wherein the component interface region further comprises a sensor for detecting the presence of gaseous bubbles within the oxygenated blood and at least one valve assembly configured for diverting the flow of the oxygenated blood to the reservoir upon detection of gaseous bubbles in the oxygenated blood by the sensor.

6 (Original). The extracorporeal blood perfusion system of claim 1, wherein the disposable assembly further defines a cardioplegia circuit for supplying a cardioplegia solution to the patient, the cardioplegia circuit including a fluid interconnection with the blood circuit for flowing at least a portion of the oxygenated blood to one of the plurality of fluid passageways for mixture with a cardioplegia solution.

7 (Original). The extracorporeal blood perfusion system of claim 1, wherein the component interface region further comprises a plurality of sensors positioned for monitoring an oxygen saturation, hematocrit and temperature of the venous blood received in the blood circuit.

8 (Original). The extracorporeal blood perfusion system of claim 1, wherein the component interface region further comprises a pressure sensor positioned for monitoring a fluid pressure of the oxygenated blood in the blood circuit.

9 (Original). The extracorporeal blood perfusion system of claim 8, wherein the control unit is operable to automatically suspend operation of the first pump when the pressure sensor detects a fluid pressure greater than a predetermined level.

10 (Original). The extracorporeal blood perfusion system of claim 1, wherein the cartridge comprises a housing including a first rigid portion connected to a second flexible portion.

11 (Original). The extracorporeal blood perfusion system of claim 10, wherein the cartridge interface region further includes a pressure sensor configured to sense fluid pressure in an internal passageway of the cartridge through the second flexible portion of the housing.

12 (Original). The extracorporeal blood perfusion system of claim 1, wherein the cartridge interface region further includes a valve actuator and the cartridge further includes a valve station, the valve station being in fluid communication with an internal passageway, the valve station having a flexible member configured to be moveable from a first position allowing fluid flow between the internal

passageways and a second position preventing fluid flow between the internal passageways, the valve actuator being configured to interface with the flexible member to cause movement of the flexible member between the first and second positions.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.